DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region
D1300B

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2909

March 31, 1997

WARNING LETTER

Patricia Nasshorn, Acting President
Direct Access Diagnostics
440 Route 22 East
Bridgewater, New Jersey 08807

File No. 97-NWJ-29

Dear Ms. Nasshorn:

During a limited inspection of your firm located at 440 Route 22 East, Bridgewater, New Jersey, conducted February 24 - 26, 1997, Investigators from this office investigated complaints regarding a promotional campaign for your product, the CONFIDE™ HIV Home Test Kit. The CONFIDE™ product is a device as defined by Section 201 (h) of the Federal Food, Drug and Cosmetic Act (Act).

During the inspection, violations of Section 501(h) of the Act and Title 21, Code of Federal Regulations, Part 820, were documented as follows:

> Adequate controls were not in place during the promotional campaign of CONFIDE™ HIV Home Test Kits, in which FEDEX envelopes and stickers were attached to the outside of kits, at point of sale. This campaign led to several complaints in which CONFIDE™ envelopes and stickers were reportedly attached to a competitor's test kits. This resulted in users of the mislabeled competitor's kits being unable to obtain test results. There were also reports of loose CONFIDE™ envelopes and stickers found at point of sale, which could have lead to additional test kits being mislabeled.

This letter is not intended to be all-inclusive of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Act and regulations promulgated under it. Federal agencies are advised of the issuance of all warning letters concerning device products so that they may take this information into account when considering the award of government contracts. Additionally, no premarket submissions for which GMP deficiencies are reasonably related, will be cleared until these have been corrected and verified.

You should take prompt action to correct this deviation. Failure to promptly take corrective measures may result in regulatory action being initiated without further notice. Further actions may include but are not limited to, seizure, injunction and/or civil penalties.

RELEASE

REVIEWED BY [signature] 3/31/97
C.O. DATE

We are in receipt of your written response, dated March 27, 1997, in which you indicated that corrective measures have been taken to resolve this issue. This involves the decision to cease the distribution of additional envelopes and stickers and an ongoing field correction at pharmacies that sell both your kit and your competitors. This field correction is planned with the cooperation of your competitor and is being conducted under the guidance of the Food & Drug Administration. We also acknowledge that future promotions involving labeling will be incorporated into the kit at an approved assembly site. We recognize your corrective measures are ongoing and will need to be verified during a future inspection of your facility. This reinspection will include a review of labeling controls and procedures.

Please notify this office in writing, within 15 working days of receipt to this letter, of any additional steps you have taken to correct this situation and include an explanation of each step taken to prevent the recurrence of similar deviations.

Your reply should be directed to the New Jersey District Office of the Food & Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey, 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,

Ray Abrahams

RAY ABRAHAMS
Acting District Director
New Jersey District

**CERTIFIED MAIL -
RETURN RECEIPT REQUESTED**

MBM:np